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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,530	09/30/2003	Hans-Hinrich Sievers	NI 158	6094
7590 08/11/2004			EXAMINER	
Klaus J. Bach 4407 Twin Oaks Drive Murrysville, PA 15668			JACKSON, SUZETTE JAMIE	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/675,530	<b>Applicant(s)</b> SIEVERS, HANS-HINRICH	
	<b>Examiner</b> Suzette J Jackson	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is FINAL.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8-10, 14-17 is/are rejected.
- 7) ☒ Claim(s) 2, 4-7 and 11-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: "Or" in the last sentence of the claim should be "are". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 8, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Philippe et al. 4,820,299. Philippe et al. discloses the invention as claimed noting figures 1-8 comprising: An artificial heart valve with an annular body; means for mounting; flap/leaflet elements which are pivotally supported by pivot support structures; wherein the annular body includes circumferentially spaced projections extending inwardly into the flow passage; wherein the projections are provided at there inwardly extending ends with pivot joints on which the flap elements are pivotally supported.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 8-9, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe et al. in view of Bokros et al. 5,843,183. Philippe et al. has been disclosed above however Philippe et al. does not disclose a recess in the valve flap/leaflet or a suture ring. Bokros et al. teaches a tri-leaflet heart valve wherein the flap/leaflet has a recess (51) and a suture ring.(35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the flap/leaflet of Philippe with a slight recess because the recess could serve as guide for surfaces and easier opening and closing of the valve and is merely a design modification. It also would have been obvious to add a sewing ring because it would further allow the surgeon to sew the device into place and is well known in the art.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe in view of Patke et al. Philippe has been disclosed above however Philippe does not disclose the specific material of titanium or titanium alloy. Patke et al. teaches that heart valves (including leaflets) can be made of numerous materials including titanium

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and/or alloy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the heart valve of Philippe out of these materials because they are well known for the durability in the prosthetic art.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe in view of Woo et al. 6,761,736. Philippe has been disclosed but does not specify the use of coating the annular body and flap with a hard material layer. Woo et al. teaches that heart valves can be coated with a hard material layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make to coat the device of Philippe et al. with a hard coating because the coating would increase durability, provide fatigue resistance and is compatibility with the substrate and is well known in the art.

***Allowable Subject Matter***

8. Claims 2, 4, 5-7, 11, 12-13, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Conclusion**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jansen 6,113,631; Jansen 6,086,612; Kaster 4,306,319; Shu et al. 2001/0025197; all show related material.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Suzette J. Jackson  
06 August 2004